# **Electronic Acknowledgement Receipt** EFS ID: 3628583 **Application Number:** 10706660 International Application Number: **Confirmation Number:** 7268 Title of Invention: Dual wire placement catheter First Named Inventor/Applicant Name: Gilbert Madrid **Customer Number:** 20995 Filer: Rabinder N. Narula/Chelsea Pearsall Filer Authorized By: Rabinder N. Narula **Attorney Docket Number:** ENDOLOG.028C2 Receipt Date: 16-JUL-2008 Filing Date: 12-NOV-2003 Time Stamp: 18:51:28 Application Type: Utility under 35 USC 111(a)

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# ENDOLOG.028C2

**PATENT** 

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant

Gilbert Madrid et al.

App. No

10/706,660

Filed

November 12, 2003

For

DUAL WIRE PLACEMENT

CATHETER

Examiner

Laura A. Bouchelle

Art Unit

3763

Conf#

7268

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Rabinder N. Narula, Reg. No. 53,371

# AMENDMENT/RESPONSE TO FINAL OFFICE ACTION

# Mail Stop AF

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

#### Dear Madame:

In response to the Final Office Action mailed on May 16, 2008, Applicant submits the following response.

Amendments to the Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 4 of this paper.



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#### AMENDMENTS TO THE CLAIMS

The listing of claims replaces all prior versions and listings of claims. Only those claims being amended herein show their changes in highlighted form, where insertions appear as underlined text (e.g., <u>insertions</u>), while deletions appear as strikethrough text (e.g., <u>deletions</u>) or enclosed in double brackets (e.g., [[deletion]]).

## 1-23. (Canceled)

24. (Currently Amended) A multilumen catheter, comprising:

an elongate, flexible tubular body, having a proximal end and a distal end;

a first lumen extending throughout the length of the tubular body, between the proximal end and the distal end, said first lumen having an open proximal access port for receiving a guidewire and an open distal access port through which said guidewire can extend;

a second lumen extending between a proximal port formed by a first cutout and a distal port formed by a second cutout;

wherein:

the proximal port and the distal port are each arranged so as to be collinear with the second lumen;

at least the distal port is spaced proximally apart from the distal end; and the catheter includes a proximal extension of the second lumen and a distal extension of the second lumen; and

the proximal and distal extensions are occluded from a remaining portion of the second lumen at the proximal and distal ports.

- 25. (Currently Amended) A multilumen catheter as in Claim 24, wherein said tubular body (26) includes a reinforcing element for reinforcing the first lumen.
- 26. (Previously Presented) A multilumen catheter as in Claim 25, wherein said reinforcing element is a braided wire.
- 27. (Previously Presented) A multilumen catheter as in Claim 24, wherein between said distal port and said distal end there is no expandable member.



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- 28. (Previously Presented) A multilumen catheter as in Claim 24, wherein said catheter has a substantially constant first diameter between said proximal port and said distal port, which is substantially equal to the diameter of a distal portion of the catheter adjacent said distal port.
- 29. (Previously Presented) A multilumen catheter as in Claim 24, wherein the proximal and distal extensions are occluded by glue plugs.
- 30. (**Previously Presented**) A multilumen catheter as in Claim 24, wherein the catheter only includes two lumens.
- 31. (Previously Presented) A multilumen catheter as in Claim 24, wherein the axis of the first lumen and the axis of the second lumen are centered about a common plane extending through the catheter.
- 32 (Previously Presented) A multilumen catheter as in Claim 31, further comprising an axially extending slit in the wall of the second lumen that extends along the common plane.
- 33. (Previously Presented) A multilumen catheter as in Claim 24, wherein the first and second cutouts are skives.
- 34. (Previously Presented) A multilumen catheter as in Claim 24, wherein the first and second cutouts each define a cylindrical surface.

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#### REMARKS

The following remarks are responsive to the Office Action dated May 16, 2008 (hereinafter, "Office Action"). Claims 24-34 remain pending in the present application, as further discussed below.

## Claim Rejections:

Claims 24, and 27-34 were rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,135,535 (hereinafter, "Kramer") in view of U.S. Patent No. 5,472,417 (hereinafter, "Martin") in view of U.S. Patent No. 6,451,043 (hereinafter, "McInnis").

Claims 25-26 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kramer in view of Martin and McInnis as applied to Claim 24, and in further in view of U.S. Patent No. 6,159,195 (hereinafter, "Ha").

As set forth in greater detail below, Applicants respectfully disagree with the Examiner's rejections and respectfully request the Examiner to reconsider and allow all of the above-listed claims in view of the following comments.

### Claims 24, and 27-34:

Claim 24 claims a multilumen catheter comprising, <u>inter alia</u>, a second lumen extending between a proximal port formed by a first cut out and a distal port formed by second cutout, wherein the catheter includes proximal and distal extensions of the second lumen, and the proximal and distal extensions are occluded from the remaining portion of the second lumen at the proximal and distal ports.

As the Examiner notes, Claim 24 differs from the disclosure in Kramer in that Claim 24 states that the distal extension is occluded from a remaining portion of the second lumen at the distal port. The Office Action also states that it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Kramer's catheter system to "include an occlusion of the distal extension as taught by Martin to prevent blood entering the area and clotting ..." Applicants submit that incorporating Martin's occlusion into Kramer's catheter system would not have been obvious to one of ordinary skill in the art at the time of Applicant's invention.

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Respectfully stated, Applicants submit that the Examiner has improperly engaged in hindsight based on Applicant's disclosure to reach the conclusion that such a combination of references would have been obvious to one of ordinary skill in the art, and has contravened the Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in KSR International Co. v. Teleflex Inc. (hereinafter, "Examination Guidelines"). As stated in the Examination Guidelines, "rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." 72 Fed. Reg. 57527, 57528-57529 (internal citations omitted). Such articulated reasoning with rational underpinning is absent from the Office Action and, for the following reasons, Applicants submit that such rational underpinning is not possible because the combination of references stated in the Office Action is not feasible.

In particular, Applicants submit that combining Martin's occlusion plug 60 with Kramer's catheter system would have rendered Kramer's catheter system inoperable. Therefore, such a combination would not have been obvious *or even feasible* to one of ordinary skill in the art. In short, Kramer's "invention is directed to a catheter system which can be used in and over-the-wire type mode and which can also allow for the exchange of either a guidewire or catheter mounted over a guidewire during intraluminal procedures such as PTCA ..." (Kramer, column 2, lines 45-49). "The catheter system of the invention generally comprises an elongated catheter body with ... a guidewire-receiving inner lumen extending within the body to the distal end thereof." (Kramer, column 2, lines 52-57).

Kramer explicitly states that the "catheter has a catheter body with two inner lumen extending essentially the length thereof, one of the lumens being a guidewire-receiving lumen and the other lumen being adapted to direct inflation fluid to the interior of a dilation balloon on the distal portion of the catheter." (Kramer, column 3, lines 7-12). With reference to Figure 1, the inflation lumen 12 terminates in the interior of an inflatable balloon 13 and is, accordingly, not configured to permit a guidewire to pass therethrough. (Kramer, column 5, lines 4-10). Additionally, with reference to Figure 1, as described in Kramer, a function of the guidewire-receiving inner lumen 14 is to receive and allow translation therethrough of a guidewire 27. (Kramer, column 5, lines 35-37; column 6, lines 5-14). Therefore, using Martin's plug 62 to

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occlude Kramer's guidewire-receiving inner lumen 14 (or inflation lumen 12) would render Kramer's catheter system inoperable for its intended purpose. Therefore, Applicants submit that it would not have been obvious to one of ordinary skill in the art to occlude Kramer's guidewire-receiving inner lumen 14 with Martin's plug 60.

Regarding dependent Claims 27-34, Applicants submit that these claims are also not unpatentable over Kramer in view of Martin and McInnis for at least the same reasons as stated above for Claim 24 (upon which Claims 27-34 depend) and also because each of Claims 27-34 recite further patentable distinctions over the cited references. Further, respectfully stated, the Examiner has omitted the discussion of how the limitations set forth in Claims 27-34 are unpatentable over Kramer in view of Martin and McInnis and has, therefore, not satisfied the requirements for supporting a § 103(a) rejection set forth in the Examination Guidelines, as discussed above.

Applicants also submit that dependent Claims 25-26 are also not unpatentable over Kramer in view of Martin, McInnis, and Ha for at least the same reasons as stated above for Claim 24 (upon which Claims 25-26 depend) and also because Claims 25-26 each recite further patentable distinctions as compared to the cited references.

Accordingly, Applicants submit that Claims 24-34 are in a condition for allowance over the references cited in the Office Action and respectfully request the Examiner to pass these claims to allowance.

#### No Disclaimers or Disavowals

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, the Applicants are not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. The Applicants reserve the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that the Applicants have made any disclaimers or disavowals of any subject matter supported by the present application.

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# Co-Pending Applications of Assignee

Applicant wishes to draw the Examiner's attention to the following co-pending applications of the present application's assignee.

Serial Number	Title	Filed
11/417,651 ENDOLOG.007C4	ENDOLUMINAL VASCULAR PROSTHESIS	05-03-2006
11/623,679 ENDOLOG.007C5	ENDOLUMINAL VASCULAR PROSTHESIS	01-16-2007
10/119,525 ENDOLOG.014C1	SELF EXPANDED BIFURCATED ENDOVASCULAR PROSTHESIS	04-08-2002
11/417,883 ENDOLOG.014C2	SELF EXPANDED BIFURCATED ENDOVASCULAR PROSTHESIS	05-03-2006
10/722,367 ENDOLOG.023CP1	GRAFT DEPLOYMENT SYSTEM	11-25-2003
10/820,455 ENDOLOG.054A	ENDOLUMENAL VASCULAR PROSTHESIS WITH NEOINTIMA INHIBITING POLYMERIC SLEEVE	04-08-2004
11/104,303 ENDOLOG.056A	METHOD AND APPARATUS FOR DECOMPRESSING ANEURYSMS	04-12-2005
11/580,201 ENDOLOG.056CP1	METHOD AND APPARATUS FOR DECOMPRESSING ANEURYSMS	10-12-2006
11/522,292 ENDOLOG.067A	MULTI-SEGMENTED GRAFT DEPLOYMENT SYSTEM	09-15-2006
11/623,022 ENDOLOG.075A	DUAL CONCENTRIC GUIDEWARE AND METHODS OF BIFURCATED GRAFT DEPLOYMENT	01-12-2007
60/947,317 ENDOLOG.081PR	GRAFT WITH ELECTRICAL SURFACE CHARGES	06-29-2007
60/981,869 ENDOLOG.085PR	STENT	10-23-2007
60/955,302 ENDOLOG.087PR	APPARATUS AND METHOD FOR RAPID RELEASE OF THERAPEUTIC AGENT INTO ANIMAL TISSUE	08-10-2007
60/987261 ENDOLOG.087PR2	APPARATUS AND METHOD FOR RAPID RELEASE OF THERAPEUTIC AGENT INTO ANIMAL TISSUE	11-12-2007
60/012,356 ENDOLOG.087PR3	APPARATUS AND METHOD FOR RAPID RELEASE OF THERAPEUTIC AGENT INTO ANIMAL TISSUE	12-07-2007
60/987268 ENDOLOG.091PR	METHOD AND AGENT FOR IN-SITU STABILIZATION OF VASCULAR TISSUE	11-12-2007
61/012,579 ENDOLOG.092PR	GRAFT WITH THERAPEUTIC AGENT	12-10-2007
12/101,863 ENDOLOG.093A	MULTI-SEGMENTED GRAFT DEPLOYMENT SYSTEM	04-11-2008
11/189,101 ENDOLOG.21CP6C2	BIFURCATION GRAFT DEPOLYMENT CATHETER	07-25-2005

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11/417,926 ENDOLOG.21CP7C2	IMPLANTABLE VASCULAR GRAFT	05-03-2006
11/764,715 ENDOLOG.21CP7CC	IMPLANTABLE VASCULAR GRAFT	06-18-2007
10/690,227 ENDOLOG.23DV1C1	SINGLE PUNCTURE BIFURCATION GRAFT DEPLOYMENT SYSTEM	10-21-2003
11/214,427 ENDOLOG.4C3C1	BIFURCATED VASCULAR GRAFT AND METHOD AND APPARATUS FOR DEPOLYING SAME	08-29-2005

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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Dated: 7-16-08

By:\_\_\_\_/ C

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